

## **REMARKS**

### **I. Preliminary Remarks**

Claim 2 has been amended to address the indefiniteness rejection and the preferred aspect of the invention wherein the tripeptide of claim 1 is an ethyl ester is presented in new claim 25.

### **II. Outstanding Rejections**

Claims 1-2, 6, 16, 18 and 20 stand rejected under 35 U.S.C. §102(b) over Lewensohn WO 01/96367 on the basis that the claims encompass the compound L-prolin-L-melaphanyl-p-Fluorophenylalanine ethyl ester in Lewensohn.

Claim 2 stands rejected as being indefinite under 35 U.S.C. §112 (second paragraph) for reciting both methyl and ethyl with ethyl being preferred.

Claim 11 stands objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form.

New Claims 23-24 are withdrawn from examination.

### **III. Patentability Arguments**

#### **A. The Rejection of Claims 1-2, 6, 16, 18 and 20 under 35 U.S.C. §102(b) over Lewensohn WO 01/96367 Should Be Withdrawn.**

The rejection of claims 1-2, 6, 16, 18 and 20 under 35 U.S.C. §102(b) over Lewensohn should be withdrawn because claim 1 is directed to a “tripeptide or an alkyl ester thereof which is connected to a drug...via its not terminal proteolytic enzyme cleavable amino acid moiety”. The term “drug” in contrast to “reactive group” or “reactive site” is defined at para. [0017] of the specification and is distinguished from the compounds or reactive groups cited by the Action. Claims 1 and 7 recite subject matters having different purposes. Claim 1 is directed to a system for the transport and delivery of drugs while claim 7 (now canceled) was directed to a reactively substituted peptide starting material suitable for performing the coupling to a drug.

The benefit of the coupling of a drug to a tripeptide according to the invention is that side effects are significantly reduced. If a drug is administered via conventional routes it is

unselectively distributed within the body. In case of drugs that are quickly metabolized, it may even be the case that no effective substance reaches the locale of desired action.

In the present case, Applicants have found that a drug can be coupled to a tripeptide and if this is done via a non terminal moiety, (thus leaving the terminal groups free for interaction) such a tripeptide can adhere to the surface of red blood cells and is rapidly transported thereon with reduced decomposition. As a consequence of the requirement that the drug loaded moiety must be cleavable by protease, delivery at protease rich sites is favored resulting in enhanced concentrations of drug at such sites and reduced concentrations at other sites with resulting improved efficacy and reduced side effects.

For these reasons, Lewensohn fails to anticipate claim 1 or claims 2, 6, 16, 18 and 20 depending therefrom and the rejection of those claims should be withdrawn. It is further submitted that the objection to claim 11 as depending from rejected base claim 1 should be withdrawn in light of the allowability of independent claim 1.

B. The Rejection of Claim 2 under 35 U.S.C. §112 (second paragraph) Should Be Withdrawn.

The rejection of claim 2 under 35 U.S.C. §112(second paragraph) for indefiniteness should be withdrawn in light of the amendment of that claim and the introduction of new claim 25 reciting that the preferred alkyl group is an ethyl group.

### CONCLUSION

For the foregoing reasons, it is submitted that each of claims 1, 2, 6, 7, 16, 18, 20 and 25 should now be allowed. Should the Examiner wish to discuss any issues of form or substance, he is invited to contact the undersigned attorney at the number below.

Dated: May 24, 2010

Respectfully submitted,

By   
Jeffrey S. Sharp

Registration No.: 31,879  
MARSHALL, GERSTEIN & BORUN LLP  
233 S. Wacker Drive, Suite 6300  
Sears Tower  
Chicago, Illinois 60606-6357  
(312) 474-6300  
Attorney for Applicant